

60. (New) The implantable medical pump of claim 41 wherein the control is an electromechanical control that receives an induced voltage in response to the control signal.

Remarks

The Office Action of December 12, 2001 has been carefully reviewed and this paper is responsive thereto. In the Examiner's action, claims 9, 15, 21 and 27 were rejected under 35 U.S.C. § 102(b) and claims 1-8, 10-14, 16-20 and 22-26 were rejected under 35 U.S.C. § 103(a). By this response, the Applicants have amended claims 9 and 15 and have added claims 33-60. No new matter has been introduced into the application. The claims as amended are believed to be in allowable condition. The following remarks traverse any remaining grounds for rejection. The Applicants respectfully request reconsideration of the application, withdrawal of the rejections and allowance of all pending claims.

Rejection Under 35 U.S.C. § 102(b) – DeCant

Claims 9, 15, 21 and 27 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,447,224 (“DeCant”). As shown in the following remarks, Applicants assert that DeCant fails to disclose, teach or suggest the invention of claims 9, 15, 21 and 27.

DeCant discloses an implantable pump apparatus that varies infusate flow rates using a microprocessor 68. For example, the microprocessor 68 may vary flow based on a pressure differential that is sensed by a transducer. Specifically, a transducer 44 senses a pressure differential between bellows capsules 58 and 62. The pressure differential is ultimately indicative of the actual infusate flow rate from chamber 24 to catheter 16. (Col. 6, lines 38-43). The microprocessor thereby closes or opens a restrictor 38 until the actual infusate flow rate

equals a programmed one. (Col. 6, lines 53-56). Alternatively, microprocessor 68 may change flow if the patient's infusion schedule calls for a change. (Col. 6, line 67 – Col. 7, line 2).

To implement the functionality of the DeCant system, continuous power by an internal battery is therefore required. (Abstract). More particularly, a battery 72 powers memory 74, transceiver 76, microprocessor 68, electromechanical actuator 73 driving variable flow restrictor 38 and the opening and closing of valve 42. (Col. 6, lines 19-34). DeCant therefore requires the use of a battery to maintain low-level power to control electronics and to provide energy for sampling flow rates and varying valve settings. (Col. 7, lines 35-41). The battery of DeCant, however, has a limited useful life and the device must be removed for servicing or replacement.

The present invention, on the other hand, is distinct from DeCant in several respects. Significantly, DeCant fails to disclose, teach or suggest the ability to change the setting of a valve (as opposed to a restrictor) in response to a control signal received via telemetry from an external source. For example, independent claim 9 recites “a passive control for changing the flow rate setting of the valve in response to a received external control signal.” (emphasis added). For example, independent claim 21 recites “a control for changing the flow rate setting of the plurality of valve in response to a received control signal.” (emphasis added). Similar limitations are present in independent claims 15 and 27. Thus, under the present invention, when it become desirable to adjust the treatment therapy provided by the implanted device, the patient and/or the physician may send via telemetry a control signal to adjust a flow rate setting of a valve. Thus, the flow rate of the implantable pump of the present invention is adjusted only when a control signal is sent via telemetry by a programmer located outside the body. (Application, page 3). Although DeCant discloses the ability to reprogram the microprocessor by telemetry (Col. 8, lines 29-35), it does not disclose, teach, or suggest the ability to provide a

control signal directly to a control to responsively change the flow rate setting of a valve. DeCant merely teaches the option to reprogram the microprocessor to change the dosage schedule, which merely suggests that drug may be delivered during other times of the day. DeCant does not disclose the ability to provide a control signal to directly adjust a valve setting to adjust the flow rate.

The present invention therefore not only allows for flow rate adjustability directly by the patient or physician, it eliminates the need for an internal battery for this purpose. (Application, page 3-5). For example, independent claim 9 recites “a passive control for changing the flow rate setting of the valve in response to a received external control signal.” (emphasis added). Similar limitations are present in independent claim 15. The useful life of the present invention is therefore not limited by an internal battery like that taught by DeCant.

Moreover, DeCant fails to disclose, teach or suggest a plurality of valves in combination with a control for changing the flow rate setting of the plurality of valves. For example, claims 21 and 27 recite “a plurality of valves for controlling the flow of fluid from the fluid reservoir ... and a control for changing the flow rate setting of the plurality of valves in response to a received control signal.” The present invention thus contemplates a plurality of valves of various types and in various combinations, controlled by a control signal, and capable of varying infusate flow rates with no requirement for power except during flow rate changes. (Application, page 5).

For the foregoing reasons, the Applicants respectfully submit that independent claims 9, 15, 21 and 27 are patentably distinct over DeCant. The Applicants therefore request withdrawal of this ground for rejection of claims 9, 15, 21 and 27.

Rejection Under 35 U.S.C. § 103(a) – Decant and Idriss

Claims 1-8, 10-14, 16-20 and 22-26 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Decant in view of U.S. Patent 5,207,666 (“Idriss”).¹ The Applicants respectfully assert that the present invention is nonobvious over DeCant in view of Idriss, and submit the following remarks.

Idriss discloses an implantable fluid metering device capable of delivering flow pulses of fluid at a predetermined rate. (Abstract). Flow rate is adjusted by changing the stroke volume of the delivery mechanism in response to an external signal. (Col. 3, lines 1-10). In other words, regulation of the delivery rate is accomplished by varying the active delivery mechanism. Moreover, Idriss teaches the use of a slider 3 retaining a shuttle 4 and an external controller 123 that “could be a microprocessor-based hand held unit which could provide information to an implanted telemetry coil via a radio frequency link. An implanted microprocessor and power supply would deliver intermittent energy to a motor that would reciprocate the slider 3” and thereby vary the rate of fluid flow in accordance with information provided through the radio frequency link. (Col. 4, lines 35-37; Col. 7, lines 47-53, emphasis added). The external controller 123 of Idriss thus transfers programming information via RF telemetry to a microprocessor and motor that, like the components of DeCant, are powered by an internal power supply.

The Office Action states that “it would have been obvious to modify DeCant, Jr. et al., by substituting for the telemetry link thereof, a radio frequency telemetry link as taught by Idriss, et al.” However, neither DeCant nor Idriss – alone or in combination – disclose, teach or suggest all the claim limitations of the present invention. See MPEP 706.02(j) (“To establish a *prima*

¹ The applicants note that this paper is responsive to the DeCant and Idriss references described at page 3 of the December 12, 2001 Office Action and its enclosed form PTO-892. This response does not address the apparently errant “Reinicke, et al.” reference at page 2 of the Office Action. Telephone messages to this effect were left with the Examiner and the Examiner’s supervisor.

facie case of obviousness, three basis criterion must be met. ... [Third], the prior art reference[s] ... must teach or suggest all the claim limitations”). For example, independent claim 1 of the present application recites “a passive regulator assembly adjustable to a plurality of flow settings”, an “induced voltage”, and “means for receiving radio frequency signals operative to maintain the induced voltage in the electromechanical control means in response to received radio frequency signals.” Neither DeCant nor Idriss disclose, teach or suggest a passive regulator assembly that is adjustable, and a programmer located outside the body capable of inducing a voltage within the pump apparatus and thereby eliminating the need for an internal battery or energy supply. (Application, pp. 3-5). Further, neither DeCant nor Idriss disclose, teach or suggest “a plurality of valves for controlling the flow of fluid from the fluid reservoir ... and a control for changing the flow rate setting of the plurality of valves in response to a received control signal,” as does the present invention.

Moreover, because DeCant and Idriss both rely on depletable internal power supplies, they contain no suggestion or motivation to modify or combine the prior art to successfully arrive at a plurality of valves, controlled by a control signal, and being capable of varying infusate flow rates with no requirement for power except during flow rate changes. (Application, page 5). See MPEP 706.02(j) (“there must be some suggestion or motivation ... to modify the reference or to combine reference teachings” and “there must be a reasonable expectation of success” in such a modification or combination). Because the prior art fails to disclose, teach or suggest the claim limitations of the present invention, and there is no suggestion or motivation to modify or combine the prior art and successfully arrive at the present invention, the present invention is nonobvious over DeCant in view of Idriss.

Finally, at least with regard to dependent claims 10-14, 16-20 and 22-26, in view of above remarks relating to the § 102(b) rejection, the Applicants respectfully submit that dependent claims 10-14, 16-20 and 22-26, which depend from and further limit claims 9, 15, 21 and 27, are patentably distinct for at least the same reasons. The Applicants therefore respectfully request withdrawal of this ground for rejection.

Newly Added Claims

Claims 33-60 have been added and are believed to be patentable over all prior art of record. Thus, claims 33-60 are believed to be in allowable condition. Favorable consideration of new claims 33-60 therefore is also earnestly requested.


CONCLUSION

For the foregoing reasons, the Applicants believe that the pending and new claims are patentable over DeCant and Idriss, alone and/or in combination. Should there be any outstanding questions of patentability, the Examiner is respectfully urged to contact the undersigned.

Respectfully submitted,

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“Version With Markings To Show Changes Made”

IN THE CLAIMS

Claims 9 and 15 have been amended as follows:

9. **(Amended)** An implantable medical pump, comprising:
- a fluid reservoir;
- a valve for controlling the flow of fluid from the fluid reservoir;
- a plurality of flow restrictors operatively coupled to the valve for providing a plurality of flow rates of the fluid from the fluid reservoir; and
- a passive control for changing the flow rate setting of the valve in response to a received external control signal.
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15. **(Amended)** An implantable medical pump, comprising:
- a fluid reservoir;
- a multi-stable valve having multiple states for providing a plurality of flow rates of fluid from the fluid reservoir;
- a flow restrictor operatively coupled to the multi-stable valve for regulating the flow rate of fluid from the fluid reservoir; and
- a passive control for changing the flow rate setting of the multi-stable valve in response to a received external control signal.